**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| MICROSPHERIX LLC,<br><br>Plaintiff,<br>v.<br><br>MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V. AND ORGANON USA, INC.,<br><br>Defendants. | Civil Action No. 2:17-cv-03984<br><br>(CCC/MF)<br><br>JURY TRIAL DEMANDED<br><br>*Electronically Filed* |

**MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V. AND ORGANON USA, INC.'S RESPONSE TO MICROSPHERIX'S MOTION TO DISMISS**

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# I.
# INTRODUCTION

Microspherix's Partial Motion to Dismiss (Dkt. 100-1) ("Motion") does not seek to exclude Merck from raising any invalidity theory or "*ground* that [Merck] raised or reasonably could have raised during [] inter partes review," as authorized by 35 U.S.C. § 315(e)(2). *Id.* (emphasis added). It has no reason to do so—Merck *has already stated to Microspherix in writing* that Merck has no intention of relitigating any grounds of invalidity already raised in the IPR proceedings. Instead, Microspherix's Motion attempts to expand IPR law well beyond its statutory language by asking the Court to issue a blanket ban on a category of *prior art*—namely, patents and printed publications—that can be relevant to multiple invalidity theories or "grounds," including those that by definition could not have been raised in an IPR.[1] But by its express terms, the IPR estoppel provision codified at 35 U.S.C. § 315(e)(2) is limited to invalidity theories or "grounds that the petitioner raised or reasonably could have raised"—and specifically, grounds based only on "prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). Courts have

[1] Under 35 U.S.C. § 311(b), a petitioner may assert invalidity in an IPR "only on the basis of prior art consisting of patents or printed publications," and not, for example, on the basis of prior art products. In its Motion, Microspherix expressly does not challenge Merck's invalidity theories based on physical prior art. *See* Mot. at 10 (reserving the right to move to strike Merck's "invalidity grounds" at a later time).

therefore repeatedly held that grounds based on prior art products or combinations of prior art products and printed publications, and even grounds based on patents or printed publications that could not "reasonably" have been raised, are explicitly outside the purview of IPR estoppel.

Microspherix *does not dispute* this law. Instead, its Motion attempts to sidestep the law by asking the Court to ban any reference to patents and printed publications—even if used to support invalidity theories or grounds that could not have been raised in IPR. This strategy has been repeatedly rejected by the courts because § 315(e)(2) does not authorize "piecemeal exclusion of the printed publications *underlying* [any] invalidity theory." *SPEX Tech. Inc. v. Kingston Tech. Corp.*, No. SACV 16-01790, 2020 WL 4342254, at *14-15 (C. D. Cal. Jun. 16, 2020) (emphasis added).

Not only is piecemeal exclusion of prior art contrary to substantive estoppel law, it is also impermissible under Rule 12(b)(6). Because Microspherix cannot allege—much less prove—that any of Merck's Counterclaims are barred in their entirety, Microspherix asks the Court to "*partially* dismiss the Second, Fourth, and Sixth Counterclaims" to preclude Merck from raising patents and publications supporting those claims. Mot. at 1 (emphasis added). But Rule 12(b)(6) does not "permit piecemeal dismissals of *parts* of claims." *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) (emphasis in original). Nor does it allow "dismissal

of *facts* rather than *claims*." *Limone v. U.S.*, 271 F. Supp. 2d 345, 364 (D. Mass. 2003) (emphasis in original). Microspherix's request that the Court issue such a "partial dismissal" is alone fatal to its Motion.

Finally, by asking this Court to resolve on the pleadings the *affirmative defense* of IPR estoppel, Microspherix's Motion turns estoppel law on its head. As the movant, *Microspherix* bears the burden to prove estoppel, and it cannot do so on the pleadings. The inherently fact-intensive nature of the IPR estoppel affirmative defense—which requires proof of, among other things, what a skilled searcher's diligent search would have found—makes it a uniquely poor candidate for resolution on a motion to dismiss. Indeed, Microspherix's estoppel arguments are based almost entirely on the 14 exhibits attached to its own Motion—none of which appear on the face of Merck's Counterclaims, and none of which can be considered for the purposes of a motion to dismiss. Microspherix therefore fails to meet its burden to prove the affirmative defense of IPR estoppel.

The Motion fares no better with respect to Merck's other counterclaims and defenses. Merck's prior invention counterclaims and defenses meet the liberal pleading requirements of Rule 8. And Microspherix's motion to strike Merck's prior commercial use defense fails quite simply because Microspherix applies the wrong law.

Each of the independent categories of defects in Microspherix's Motion—misstatements of substantive law, improper procedural posture, and impermissible reliance on facts outside of the pleadings—is sufficient basis, alone, to deny the Motion in its entirety. Taken together, they warrant skepticism of Microspherix's intentions and diligence in filing the Motion.

## II. ARGUMENT

### A. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint need only "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[A]ll allegations in the complaint must be accepted as true, and the plaintiff must be given the benefit of every favorable inference to be drawn therefrom." *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011) (quoting *Kulwicki v. Dawson*, 969 F.2d 1454, 1462 (3d Cir. 1992)); *Weimer v. Cnty. Of Fayette, Pennsylvania*, 972 F.3d 177, 180 (3d Cir. 2020).

Moreover, "resolution of factual issues . . . is inappropriate on a motion to dismiss." *D'Agostino v. Appliances Buy Phone, Inc.*, 633 Fed. Appx. 88, 94 (3d Cir. 2015). Instead, in deciding a motion to dismiss, courts consider "only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

With respect to defenses, "Rule 12(f) motions to strike are disfavored." *Sugg v. Virtusa Corp.*, No. 18-cv-8036-MAS-PEA, 2019 WL 1924855, at *2 (D.N.J. Apr. 30, 2019). A motion to strike should be denied *unless* the material to be stricken bears "*no possible relation* to the controversy and may cause prejudice to one of the parties." *Hanover Ins. Co. v. Ryan*, 619 F. Supp. 2d 127, 133 (E.D. Pa. 2007) (emphasis added); *see Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 188 (3d Cir. 1986) (motions to strike should not be granted unless the relevant insufficiency is "clearly apparent").

**B. Microspherix does not seek IPR estoppel and is not entitled to the relief it seeks.**

Merck has already stated to Microspherix in writing that Merck does not intend to raise in this litigation any grounds already raised during the IPR. *See* Aug. 24, 2020 Email from A. Blythe to M. Sernel (Yang Decl., Ex. A). And Microspherix does not dispute in its Motion that Merck is entitled to raise *other* invalidity grounds that could not reasonably have been raised in the IPR—including those based on prior art products. But Microspherix asks the Court to "partially dismiss the Second, Fourth, and Sixth Counterclaims" (Mot. at 1) and estop Merck from relying on any patents and publications to support its clearly permissible invalidity grounds.

The Motion should be denied for at least three independent reasons. First, IPR estoppel law is limited to grounds of invalidity and does not authorize piecemeal exclusion of prior art underlying those grounds. Likewise, Rule 12(b)(6) does not

provide a vehicle for dismissal of parts of claims or the facts underlying those claims, as sought by Microspherix here. Finally, Microspherix bears the burden of proving estoppel as an affirmative defense, and fails to meet its burden on the pleadings.

**1. Microspherix misapplies IPR estoppel law by seeking exclusion not of grounds for invalidity, but prior art underlying those grounds.**

Under 35 U.S.C. § 315(e)(2), "[t]he petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision . . . may not assert . . . in a civil action . . . that the claim is invalid *on any ground* that the petitioner raised or reasonably could have raised during that inter partes review." *Id.* (emphasis added). By its very terms, IPR estoppel under § 315(e) bars only *grounds* of invalidity—meaning "the basis or bases on which a petitioner challenges a claim," such as a combination of "prior art references A, B, and C." *California Inst. Of Tech. v. Broadcom Ltd.*, No. CV 16-3714, 2018 WL 7456042, at *4, *7 n.7 (C.D. Cal. Dec. 28, 2018). Patent law distinguishes such "grounds for invalidity" from "each item of prior art" used to support the grounds. L. Pat. R. 3.3 (requiring invalidity contentions to disclose "grounds for invalidity" and, separately, "each item of prior art"); *see* 35 U.S.C. § 312(a) (requiring a petition for IPR to contain "the grounds on which the challenge to each claim is based," and, separately, the prior art "that supports the grounds for the challenge").

The only grounds of invalidity that may be raised in an IPR are those based solely on "patents and printed publications"—meaning that grounds of invalidity that include a physical prior art product or system (or any other prior art other than a patent or printed publication) by definition cannot be raised in an IPR. 35 U.S.C. § 311(b). Courts have therefore held repeatedly that IPR estoppel under § 315(e)(2) does not apply to invalidity grounds "based on physical prior art, whether standing alone *or in combination with a printed reference*." *Microchip Tech. Inc. v. Aptiv Serv. US LLC*, No. 1:17-cv-01194-JDW, 2020 WL 4335519, at *4 (D. Del. Jul. 28, 2020) (emphasis added); *see Medline Indus., Inc. v. C.R. Bard., Inc.*, No. 17 C 7216, 2020 WL 551232, at *4 (N. D. Ill. Sept. 14, 2020) ("[T]he language of § 315(e)(2) does not estop an IPR petitioner's use in litigation of an invalidity theory that relies upon a product as a prior art reference because a prior art product cannot be used as a reference to challenge the validity of a patent claim in an IPR."); *Zitovault, LLC v. Int'l Bus. Machines Corp.*, No. 3:16-CV-0962-M, 2018 WL 2971178, at *4 (N.D. Tex. Apr. 4, 2018) (Lynn, C.J.) (rejecting estoppel of grounds over prior art systems because defendants "could not have raised prior art systems, such as products and software, during IPR proceedings"); *Polaris Indus., Inc. v. Arctic Cat Inc.*, No. 15-4474, 2019 WL 3824255, at *3 (D. Minn. Aug. 15, 2019) (declining to apply IPR estoppel to "combinations . . . [that] include physical vehicles"); *SPEX*, 2020 WL 4342254, at *14-15 (same).

The recent case of *SPEX Tech. v. Kingston Tech. Corp.* is particularly instructive. In that case—as in this one—plaintiff "d[id] not argue that [defendant's] system invalidity theories should themselves be estopped." 2020 WL 4342554, at *15. Plaintiff "instead argue[d] that [defendant] should be precluded from relying on some, but not all, of its cited documents to underpin its system invalidity theories." *Id.* Observing that "IPR estoppel is focused on '*grounds*' that were 'raised or reasonably could have [been] raised' during IPR," the *SPEX* court held that "reliance on some printed publications in an overall collection of documents being used to describe a system invalidity theory [or *ground*] should not lead to estoppel of the overall system invalidity theory itself, nor piecemeal exclusion of the printed publications underlying that invalidity theory." *Id.* (emphasis added).

Like the plaintiffs in *SPEX*, Microspherix's Motion does not argue that Merck is estopped from asserting any particular grounds or theories of invalidity in the Counterclaims. Merck's Counterclaims do not identify—and Rule 8 does not require—any specific grounds of invalidity or combinations of invalidating references. *See Teirstein v. AGA Med. Corp.*, No. 6:08-cv-14, 2009 WL 704138, at *3 (E.D. Tex. Mar. 16, 2009) (holding that "neither *Twombly*, nor Rule 8" require a counterclaimant for a declaratory judgment of invalidity to plead "any prior art that would invalidate" the patents at issue); *see also O2 Micro Int'l. Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1365 (Fed. Cir. 2006) (holding that "the Federal

Rules require only notice pleading by the claimant," and "discovery is designed to allow the defendant to pin down the plaintiff's theories of liability"). Merck's Counterclaims instead list, by way of example, prior art references, products, and systems that, alone or in combination with one another, render Microspherix's patents invalid. *See, e.g.* Dkt. 90, ¶ 31 (identifying "prior art systems and products sold under the tradenames Implanon®, Norplant®, Jadelle®, Viadur®, Estring®, Progestasert®, Septopal®, Palmaz-Schatz® Stent, and prior art systems and products substantially similar thereto").

Microspherix does not dispute in its Motion that Merck is entitled to raise grounds for invalidity, at a minimum, based on prior art products and systems, and/or combinations of prior art products and systems with patents and printed publications. *See* Mot. at 7-8 (omitting prior art products referenced in Merck's Counterclaims from the scope of the Motion). Instead, like the plaintiff in *SPEX*, Microspherix attempts to make an end-run around estoppel law by arguing that Merck "should be precluded from relying on some, but not all, of its cited documents"—namely, all patents and prior publications—even though such patents and publications can be combined with prior art products and systems to invalidate Microspherix's patents. *See SPEX*, 2020 WL 4342254, at *15; *Microchip*, 2020 WL 4335519, at *4; *Medline*, 2020 WL 551232, at *4; *Zitovault*, 2018 WL 2971178, at *4; *Polaris*, 2019 WL 3824255, at *3.

Because such an interpretation runs directly contrary to the text of § 315(e)(2), Microspherix's Motion should be dismissed.

**2. Rule 12(b)(6) does not permit "partial" dismissal of a claim.**

Piecemeal dismissal of prior art references in Merck's Counterclaims is not only improper under 35 U.S.C. § 315(e)(2), it is also impermissible under Rule 12(b)(6). Apparently recognizing that it has no basis to seek dismissal of any of Merck's Counterclaims in its entirety, Microspherix instead asks the Court to "*partially* dismiss the Second, Fourth, and Sixth Counterclaims," Mot. at 1 (emphasis added), "to the extent" that these Counterclaims are supported by "patents or printed publications or any combination thereof." Dkt. 100-17, ¶ 1. Rule 12(b)(6), however, does not permit "partial" dismissal of a claim or the facts underlying a claim.

Unlike summary judgment motions under Rule 56, which may be brought on any "claim or defense – or [] *part* of each claim or defense," Fed. R. Civ. P. 56(a) (emphasis added), motions to dismiss under Rule 12(b)(6) may only be brought on an entire "*claim* for relief." Fed. R. Civ. P. 12(b)(6) (emphasis added). In other words, "[a] motion to dismiss under Rule 12(b)(6) doesn't permit piecemeal dismissals of *parts* of claims." *BBL*, 809 F.3d at 325 (emphasis in original); *Doe v. Napa Valley Unified Sch. Dist.*, No. 17-cv-03753-SK, 2018 WL 4859978, at *2 (N.D. Cal. Apr. 24, 2018) ("By its own terms, there does not appear to be any way

to grant partial dismissal of a claim under Fed. R. Civ. P. 12(b)(6).") (quoting *In re Netopia, Inc., Sec. Litig.*, No. C-04-03364 RMW, 2005 WL 3445631, at *3 (N.D. Cal. Dec. 15, 2005)).

Likewise, Rule 12(b)(6) may not be used to strike specific facts or allegations supporting a claim "if the *claim* otherwise survives." *Redwind v. Western Union, LLC*, No. 3:18-cv-02094, 2019 WL 3069864, at *4 (D. Or. Jun. 21, 2019) (emphasis added); *see Limone*, 271 F. Supp. 2d at 364 (denying motion to dismiss where defendant "seems to seek dismissal of *facts* rather than *claims*, which Rule 12 does not contemplate") (emphasis in original); *Thompson v. Paul*, 657 F. Supp. 2d 1113, 1129 (D. Ariz. 2009) ("The Court is unaware, however, of any situation in which a Rule 12(b)(6) motion may be used to strike certain *allegations* in support of a claim, where the underlying *claim* itself is not challenged.") (emphasis added).

Instead, Federal Rule of Civil Procedure 8 is clear that a counterclaimant may assert alternative factual theories to support each claim, and "the pleading is sufficient if any one of [those alternative theories] is sufficient." Fed. R. Civ. P. 8(d). "[T]he question at [the motion to dismiss] stage is simply whether the complaint includes factual allegations that state a plausible claim for relief." *BBL*, 809 F.3d at 325. In seeking only "partial" dismissal of Merck's Second, Fourth, and Sixth Counterclaims, Microspherix's motion implicitly concedes that at least *part* of each claim survives. For that reason alone, Microspherix's request for partial

dismissal of "certain allegations" or "facts" supporting Merck's claims must be denied. *Redwind*, 2019 WL 3069864, at *4.

**3. Microspherix has not met its burden to prove the affirmative defense of estoppel.**

Lastly, Microspherix's Motion should be denied for the additional and independent reason that it improperly asks this Court to resolve the affirmative defense of IPR estoppel on a motion to dismiss, based on information outside the four corners of Merck's Counterclaims and without the benefit of a developed factual record.

**a. Estoppel is not properly raised on a motion to dismiss.**

Like other forms of estoppel, "the estoppel bar under 35 U.S.C. § 315(e)(2) is an affirmative defense . . . that must be raised in the first instance by the party seeking to invoke the bar"—in other words, Microspherix. *Palomar Techs., Inc. v. MRSI Sys., LLC*, No. CV 18-10236-FDS, 2020 WL 2115625, at *4 (D. Mass. May 4, 2020); *see United States v. Asmar*, 827 F.2d 907, 912 (3d Cir. 1987) ("The burden of proof is on the party claiming estoppel."). As the movant, Microspherix "bears the burden of demonstrating that estoppel applies under 35 U.S.C. § 315(e)(2)." *Novartis Pharm. Corp. v. Par Pharm. Inc.*, No. CV 14-1289-RGA, 2019 WL 9343055, at *1 (D. Del. Apr. 11, 2019); *Wi-LAN Inc. v. LG Elecs., Inc.*, 421 F. Supp. 3d 911, 925 (S.D. Cal. 2019) (same); *Vaporstream, Inc. v. Snap Inc.*, No. 2:17-CV-00220-MLH-KSX, 2020 WL 136591, at *23 (C.D. Cal. Jan. 13, 2020) (same). And

because "[t]he facts necessary to establish an affirmative defense must generally come from matters outside of the complaint," the Third Circuit has made clear that "affirmative defenses should be raised in responsive pleadings, not in pre-answer motions brought under Rule 12(b)." *Worldcom, Inc. v. Graphnet, Inc.*, 343 F.3d 651, 657 (3d Cir. 2003). Doing so permits the court to decide such defenses upon "further development of the record," *id*.—in other words, after plaintiff has had an opportunity through discovery to "pin down the defendant's theories of defense." *O2 Micro*, 467 F.3d at 1365.

IPR estoppel, in particular, is a fact-intensive defense. To establish its entitlement to IPR estoppel, Microspherix must prove, with competent evidence, what grounds Merck "reasonably could have raised" during *inter partes* review, 35 U.S.C. § 315(e)(2)—meaning what "a skilled searcher's diligent search would have found." *Clearlamp, LLC v. LKQ Corp.*, No. 12 C 2533, 2016 WL 4734389, at *9 (N.D. Ill. Mar. 18, 2016); *Novartis Pharm.*, 2019 WL 9343055, at *2 ("Prior art 'reasonably could have been raised' when 'a skilled searcher conducting a diligent search reasonably could have been expected to discover' the prior art."). "[T]he inquiry on the objective prong [of § 315(e)(2)] is whether it is more probable than not that a skilled searcher conducting a diligent search reasonably could have been expected to discover the reference." *Palomar*, 2020 WL 2115625, at *4. As one court has described, "[o]ne way to show what a skilled search would have found

would be (1) to identify the search string and search source that would identify the allegedly unavailable prior art and (2) present evidence, likely expert testimony, why such a criterion would be part of a skilled searcher's diligent search." *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 603 (D. Mass. 2018).

Unsurprisingly, courts rarely decide such factual questions on a motion to dismiss under Rule 12(b)(6), where the court's analysis is limited to pleadings that must be accepted as true. *Pension*, 998 F.2d at 1192. Microspherix's Motion does not cite a single case deciding the IPR estoppel issue in the 12(b)(6) context, and Merck is likewise unaware of any. *See, e.g.*, Mot. at 8-9 (citing *Palomar Techs., Inc. v. MRSI Sys., LLC*, 373 F. Supp. 3d 322, 329-31 (D. Mass. 2019) (decided on summary judgment)); *Biscotti Inc. v. Microsoft Corp.*, No. 2:13-CV-01015-JRG-RSP, 2017 WL 2526231, at *8 (E.D. Tex. May 11, 2017) (same); *Milwaukee Elec. Tool Corp. v. Snap-On Inc.*, 271 F. Supp. 3d 990, 1030–31 (E.D. Wis. 2017) (same); *Verinata Health, Inc. v. Ariosa Diagnostics, Inc.*, No. 12-cv-05501-SI, 2017 WL 235048, at *3–4 (N.D. Cal. Jan. 19, 2017) (decided on motion to strike invalidity contentions). Notably, in the *Palomar* case relied on by Microspherix, *see, e.g.*, Mot. at 8, the court held a three-day evidentiary hearing with fact and expert witness testimony before concluding—contrary to the allegations in Microspherix's Motion—that IPR estoppel *did not bar* invalidity grounds based solely on prior art printed publications because "a skilled researcher conducting a diligent invalidity

search . . . reasonably could not have been expected to discover" the publications at issue at the time the IPR petition was filed due to the "difficulty of the search here." 2020 WL 2115625, at *15-16.

**b. Microspherix's Motion fails to prove its estoppel affirmative defense with competent evidence.**

Microspherix makes no secret of its reliance on facts outside of the pleadings in its motion to dismiss—attaching *14 exhibits*, comprising *681 pages* of records from the *inter partes* review proceedings and discovery responses in this action. *See, e.g.* Mot. at 7-10. None of these may be considered in resolving its motion to dismiss. *Pension*, 998 F.2d at 1192 ("To decide a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record.").

The cases cited by Microspherix are not to the contrary. Microspherix argues that the Court may properly consider the IPR records attached to its Motion as "matter[s] of public record." Mot. at 8, n.4. Not so. In the sole case cited by Microspherix in the context of IPR records, the Eastern District of Michigan considered whether the patent infringement counts pleaded in a complaint were "implausible under *Twombly* and *Iqbal*." *Choon's Design, LLC v. Zenacon, LLC*, No. 2:13-cv-13568, 2015 WL 539441, at *5 (E. D. Mich. Feb. 9, 2015); see Mot. at 8, n.4. Microspherix's Motion here, however, does not challenge the sufficiency of Merck's invalidity counterclaims under *Twombly* and *Iqbal*. Rather, Microspherix

asks the Court to dismiss Merck's counterclaims based on the merits of its IPR estoppel defense—an affirmative defense on which Microspherix bears the burden of proof and which ordinarily must be raised in a responsive pleading. *See* Section II.B.3.a, *supra*. Under such circumstances, the Third Circuit has made clear: "When a district court dismisses [a claim] on the basis of an affirmative defense [like IPR estoppel] . . . we will affirm *only when* the defense is apparent on the face of the complaint and documents relied on in the complaint." *Bohus v. Restaurant.com, Inc.*, 784 F.3d 918, 923 (3d Cir. 2015) (citations and punctuation omitted) (emphasis added); *see Albritton v. Acclarent*, No. 3:16-cv-03340-M, 2017 WL 6628122, at *2 (N. D. Tex. Dec. 27, 2017) (Lynn, C.J.) (citing *Scanlan v. Texas A & M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003)) (declining to consider IPR records in deciding a motion to dismiss because "[t]he proffered material is not part of the [complaint], and thus is outside of the scope of the pleadings the Court considers under Fed. R. Civ. P. 12(b)(6)."). Neither of these criteria is met here, where Microspherix relies on 14 exhibits attached to its Motion that are neither referred to nor relied on in Merck's Counterclaims. *Bohus*, 784 F.3d at 923.

Microspherix's argument that the Court may consider Merck's Invalidity Contentions because they are "integral to" Merck's counterclaims and defenses is also wrong. Mot. at 9 n.6. The narrow "integral or explicitly relied upon" exception applies when plaintiff's claims "are based on" a document not attached to the

complaint, such that a plaintiff cannot "survive a motion to dismiss simply by failing to attach a *dispositive* document on which it *relied*." *Pension*, 998 F.2d at 1196 (emphasis added). Here, however, Merck's Counterclaims are not *based on* its Invalidity Contentions where they do not "quote from," refer to, or "even mention" the Invalidity Contentions. *Stratechuk v. Board of Educ.*, 200 Fed. Appx. 91, 94 (3d Cir. 2006).[2] Therefore, they cannot be considered.

As the movant, Microspherix bears the burden to prove the affirmative defense of estoppel. Microspherix has not offered—and cannot offer—competent evidence to meet its burden in its motion to dismiss. Microspherix's Motion must therefore be denied.

**4. Estoppel is not appropriate on Merck's invalidity defense.**

For essentially the same reasons, Microspherix's request that the Court "partially strike Merck's Second Defense" of invalidity based on IPR estoppel should also be denied. *See* Mot. at 11. Motions to strike under Rule 12(f) are "disfavored," *Sugg*, 2019 WL 1924855, at *2, and movants face a higher bar under Rule 12(f) than even under Rule 12(b)(6). *Bos. Sci. Corp. v. Edwards Lifesciences Corp.*, No. CV 16-275-SLR-SRF, 2017 WL 781046, at *2 (D. Del. Feb. 28, 2017)

[2] And, because the Invalidity Contentions are not "integral or explicitly relied upon" in Merck's Counterclaims, they cannot be considered on a motion to dismiss, regardless of whether authenticity is disputed. *Stratechuk*, 200 Fed. Appx. at 94 (court "erred in considering" document that was not integral to the complaint "even assuming [the document] is a public record").

(affirmative defenses need not even meet the requirements of *Iqbal*/*Twombly*). An affirmative defense "must only provide the opponent fair notice of the issue involved." *Tyco Fire Prod. LP v. Victaulic Co.*, 777 F. Supp. 2d 893, 903 (E. D. Pa. 2011). "Under this standard, Defendant's affirmative defense is plainly satisfactory to the extent it avers 'invalidity.' It provides Plaintiff with notice that Defendant anticipates defending this suit on grounds of invalidity, the details of which Plaintiff can flesh out through discovery." *Id.*

Here, in addition to suffering from the same legal defects that plague its motion to dismiss, Microspherix's Motion fails to meet its high burden to strike Merck's Second Defense of invalidity. *Id.* In fact, Microspherix's Motion is devoid of any allegation of prejudice stemming from Merck's Second Defense. The Motion should therefore be denied.

### C. Merck has adequately pleaded prior invention under 35 U.S.C. § 102(g)(2).

Merck's Counterclaims also assert prior invention under 35 U.S.C. § 102(g)(2)—both as a counterclaim for declaratory judgment and as an affirmative defense to Microspherix's infringement claims. Merck Counterclaims properly plead prior invention by alleging, *inter alia*, that: (1) "Merck itself began developing the Nexplanon® implant (the very product Microspherix infringes its patents) more than 18 months before the earliest Kaplan patent application was filed"; (2) "[b]y no later than March 1999, Merck began conducted what Merck documents describe as

'Feasibility Experiments for the Development of an X-ray visible Implant'"; (3) "[t]he 1999 study concluded that the development of an X-ray visible implant was possible without major problems"; (4) "[o]ver the next few years, Merck worked continuously . . . on the development of both Implanon® and Nexplanon®"; and, (5) "[b]y May 2000, scientists at Merck had begun experimenting with different designs for an X-ray visible implant, including the design ultimately adopted." Dkt. 90 at 41–42.

**1. Merck has properly pleaded prior invention counterclaims.**

Microspherix asks the Court to dismiss Merck's prior invention counterclaims for prior invention under Section 102(g)(2), on the basis that Merck does not specifically plead that the invention happened "in this country." Mot. at 12. This argument fails. The law does not require—and none of the cases cited by Microspherix hold—that Merck must plead with particularity the specific "place of conception and/or reduction to practice" at this stage of the proceedings. Mot. at 13. Unlike fraud claims brought under Rule 9(b), Merck's prior invention Counterclaims are evaluated under Rule 8, and "need not include 'the who, what when, where, and how' as is required in fraud [claims]." *Dannenbring v. Wynn Las Vegas, LLC*, 907 F. Supp. 2d 1214, 1218 (D. Nev. 2013); *see Gibson v. Yackeren*, No. 11-cv-294S, 2013 WL 3338645, at *4 (W.D.N.Y. Jul. 2, 2013) (same). Even under the heightened pleading standard of Rule 9(b) applicable to fraud claims and inequitable

conduct, "the Third Circuit does not require a party to plead the date, time, *or place* of the inequitable conduct, so long as the pleadings 'supply the adverse party with notice of the precise conduct alleged.'" *Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, 247 F.R.D. 445, 451 (D.N.J. 2007). Under the more liberal pleading requirements of Rule 8, Merck's allegations are sufficient if they merely "state a claim to relief that is plausible on its face," *Twombly*, 550 U.S. at 570—a standard that is met by Merck's "nearly four full pages in its Answer and Counterclaims discussing alleged prior inventions," Mot. at 13.

Specifically, Merck's Counterclaims allege that "scientists at Merck" experimented, designed, and "worked continuously" to develop the Nexplanon® implant. Dkt. 90 at 42. The "Merck" entities are defined in the Counterclaims to include Merck Sharp & Dohme Corp. and Organon USA, Inc.—two U.S. companies who have maintained employees in this country during the entire relevant time period. *Id.* at 36. Indeed, the Counterclaims allege that Merck was ultimately awarded a patent in the United States related to its development of Nexplanon®. *Id.* at 42. "[D]raw[ing] all reasonable inferences" in Merck's favor, Merck has adequately pleaded a prior invention in this country. *Weimer*, 972 F.3d at 180.[3]

[3] Should the Court require any additional detail on the factual allegations underlying Merck's prior invention counterclaim, leave to amend should be granted. *New York Cent. Mut. Ins. Co. v. Edelstein*, 637 Fed. Appx. 70, 74 (3d Cir. 2016) ("Generally, before dismissing a complaint, a district court should grant leave to amend unless it determines that amendment would be futile.").

Tellingly, Microspherix attempts to patch the defects in its motion to dismiss by relying on Merck's *interrogatory responses* in this case to argue that "in fact" the prior invention was not "conceived or reduced to practice in the United States." Mot. at 13. Microspherix's prior invention argument is a summary judgment motion in disguise—asking this Court to adjudicate the facts of Merck's prior invention counterclaim based solely on interrogatory responses, before the close of discovery. Microspherix's explicit reliance on the "facts cited by Merck" in interrogatory responses, *id.*, is sufficient reason alone to deny its motion to dismiss. *See Pension*, 998 F.2d at 1196 (in deciding a motion to dismiss, courts consider "only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record").

**2. Merck has properly pleaded prior invention defenses**

For all of the same reasons, Microspherix's motion to strike the parallel prior invention defenses should be denied. *Edwards*, 2017 WL 781046, at *2 (holding that affirmative defenses are subject to more liberal pleading requirements than claims and need not meet *Twombly/Iqbal*).

In addition, Microspherix suffers no prejudice from Merck's prior invention defenses. *See Ryan*, 619 F. Supp. 2d at 133. The only prejudice alleged in Microspherix's Motion is that, if Merck is permitted to proceed with these defenses, "Microspherix would be forced to conduct international discovery . . . to uncover

facts regarding alleged activities that took place, at the earliest, over twenty years ago." Mot. at 12, n. 12. This argument lacks credibility where (1) Microspherix is suing Merck for infringement of a patent allegedly filed 20 years ago, putting discovery from that time period squarely at issue in this case; and (2) Microspherix has named N.V. Organon, a foreign company, as a defendant in this case, necessarily implicating foreign discovery. *See* Dkt. 90 at 39.

In any event, the law is clear that "[a] mere desire for a more leisurely discovery schedule is not the type of prejudice that warrants striking affirmative defenses." *In re Ryckman Creek Resources, LLC*, No. 16-10292 (KJC), 2017 WL 548185, at *12 (D. Del. Feb. 8, 2017). Likewise, "[t]he fact that some foreign discovery may be required is not a basis for finding prejudice." *In re Nat'l Media Sec. Litig.*, No. Civ. A. 93-2977, 1994 WL 649261, at *3 (E.D. Pa. Nov. 18, 1994). Microspherix's Motion should therefore be denied.

**D. Merck has adequately pleaded prior commercial use.**

Finally, Microspherix moves to strike Merck's Ninth Defense, Prior Commercial Use under 35 U.S.C. § 273, based on its contention that "a defense under Section 273 is specifically limited to patents involving methods of doing or conducting business." Mot. at 14. That is not what 35 U.S.C. § 273 requires—and it has not so required for almost a decade. Microspherix's Motion should be denied

because it incorrectly applies the version of 35 U.S.C. § 273 that existed before its amendment by the America Invents Act ("AIA") in 2011.

**1. Microspherix's Motion applies the wrong law.**

The AIA is a federal statute enacted on September 16, 2011 that amended various provisions of the Patent Act. The different sections of the AIA specify their respective effective dates, based alternatively on a patent's filing date or issuance date. Microspherix's Motion alleges that "pre-AIA Section 273 applies" to Merck's defense because "[t]he effective filing date of the Asserted Patents is before March 16, 2013—the date the America Invents Act (AIA) took effect." *Id.* at 13 n.9 (emphasis added). To the contrary, the AIA explicitly states that its amendments to 35 U.S.C. § 273 "shall apply to any patent *issued* on or after the date of *the enactment* of this Act [on September 16, 2011]." America Invents Act, Pub. Law 112-29, H.R. 1249, § 5(c) (2011) (emphasis added). Because each of the Asserted Patents was issued well after September 2011, each is subject to 35 U.S.C. § 273 as amended by the AIA.

Under AIA Section 273, Microspherix's argument that the prior commercial use defense is "limited to patents involving methods of doing or conducting business" is flatly wrong. *See* Mot. at 14 (citing to *Sabasta v. Buckaroos, Inc.*, 507 F. Supp. 2d 986, 1003–04 (S.D. Iowa 2007) (interpreting the pre-AIA version of Section 273)). Unlike the pre-AIA version of the same statute, the AIA amendment

to Section 273 explicitly applies to "a process," *as well as* "a machine, manufacture, or *composition of matter* used in a manufacturing or other commercial process." 35 U.S.C. § 273(a) (emphasis added). In fact, the legislative history of the AIA is clear that the *primary* change to Section 273 was that "the prior-use defense may be asserted against any patent (not just method patents)." 112 H Rep. No. 98(I), at 44 (2011), 2011 WL 2150541, at *55 (2011).

Applying the correct legal framework, AIA § 273 clearly covers Merck's prior commercial use of Nexplanon®, a composition of matter. 35 U.S.C. § 273(a). Indeed, AIA § 273(c)(1) is explicit that the prior commercial use defense extends to products, like Nexplanon®, that are subject to "premarketing regulatory review" for "safety or efficacy." Under § 273(c)(1), such products are "deemed to be commercially used" by no later than "the date the application was initially submitted for the approved product." 35 U.S.C. § 273(c)(1); 35 U.S.C. § 156(g)(1)(B).

**2. Merck has provided fair notice of its defense.**

Microspherix's cursory allegation that it lacks "fair notice" of Merck's prior commercial use defense likewise fails to persuade. Mot. at 14. "[A]ffirmative defenses pleaded pursuant to Rule 8(c) are not held to the same pleading requirements as claims for relief brought in accordance with Rule 8(a)." *Edwards*, 2017 WL 781046, at *2. Rather, "[a]n affirmative defense must merely provide fair notice of the issue involved." *Id.* Merck meets this obligation by "provid[ing]

sufficient information to put [Microspherix] on notice that [Merck] is asserting a prior use defense to pursuant to § 273, and more detailed facts supporting that defense will be revealed during the course of fact discovery." *Id.* Microspherix's request under Rule 12(f) to strike Merck's Ninth Defense should therefore be denied.

## III.
## CONCLUSION

Microspherix's Partial Motion to Dismiss Defendants' Second, Fourth, and Sixth Counterclaims and Strike Defendants' Second and Ninth Defenses—replete with misstatements of substantive law, procedural defects, and impermissible reliance on facts outside the pleadings—is wholly lacking in merit, and borders on a waste of the Court's and Merck's resources. Because Merck has adequately pleaded its counterclaims and defenses, Merck respectfully requests that the Court deny the Motion in its entirety and grant Merck any such further relief as the Court may deem just and appropriate.

Date: November 2, 2020

Respectfully submitted,

**GIBSON, DUNN & CRUTCHER, LLP**

Tracey B. Davies (*admitted pro hac vice*)
Betty X. Yang (*admitted pro hac vice*)
GIBSON, DUNN & CRUTCHER, LLP
2001 Ross Avenue, Suite 2100
Dallas, TX 75201
Tel: (214) 698-3100
Fax: (214) 571-2900
tdavies@gibsondunn.com
byang@gibsondunn.com

Y. Ernest Hsin (*admitted pro hac vice*)
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street
San Francisco, CA 9410575201
Tel: (415) 393-8200
ehsin@gibsondunn.com

Andrew P. Blythe (*admitted pro hac vice*)
GIBSON, DUNN & CRUTCHER, LLP
333 South Grand Avenue
Los Angeles, CA 90071
(213) 229-7000
ablythe@gibsondunn.com

**McCARTER & ENGLISH, LLP**

*/s/ John E. Flaherty*

John E. Flaherty
Cynthia Stencel Betz
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Tel: (973) 622-4444
Fax: (973) 624-7070
jflaherty@mccarter.com
cbetz@mccarter.com

*Attorneys for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that on November 2, 2020, I caused a true and correct copy of the foregoing document to be filed on the Court's electronic filing system, which will provide notice to and constitutes service on Plaintiff's counsel of record.

*/s/ John E. Flaherty*
John E. Flaherty